

FOR US POSTAL SERVICE DELIVERY: Office for Human Research Protections 6100 Executive Boulevard, Suite 3B01 National Institutes of Health (MSC 7507) Rockville, Maryland 20892-7507 FOR HAND DELIVERY OR EXPRESS MAIL:

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July 31, 2000

Dale M. Landi, Ph.D. Vice President for Research Office of the Provost University at Buffalo State University of New York 516 Capen Hall Buffalo, New York 14260-1611

RE: Human Subject Protections Under Multiple Project Assurance (MPA) M-1270

Dear Dr. Landi:

The Office for Human Research Protections (OHRP) has received your July 19, 2000 letter reporting the suspension of five Federally supported research projects by the University at Buffalo, State University of New York, (UB) pending continuing review by the Millard Fillmore Hospital Institutional Review Board (IRB).

Based upon its review of this report, OHRP finds that UB has implemented the actions required by OHRP in its June 23, 2000 letter. As a result there should be no further need for OHRP involvement in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination. OHRP assumes that enrollment of subjects in the suspended research will not resume until the Millard Fillmore Hospital IRB conducts substantive and meaningful_continuing review of these projects and re-approves them.

OPRR appreciates your continued commitment to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely.

Michael A. Carome, M.D.

Chief, Compliance Oversight Branch
Division of Human Subject Protections

cc: Provost David J. Triggle, University at Buffalo, State University of New York

Dr. Allen Goldfarb, Chair, MFH IRB

Dr. Melody H Lin, OHRP

Dr. J. Thomas Puglisi, OHRP

Dr. Clifford C. Scharke, OHRP

Dr. Sandy Leikin, OHRP

Dr. Katherine Duncan, OHRP

Ms. Freda Yoder, OHRP